UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS DIRECTIVE	5000.4	11/17/08

PERFORMING THE REVIEW PORTION OF 01B02 (PRE-OPERATIONAL SANITATION VERIFICATION) IN RAW AND READY-TO-EAT PRODUCT PROCESSING OPERATIONS

I. PURPOSE

This directive provides instruction to inspection program personnel (IPP) regarding how to perform the Review portion of PBIS Procedure 01B02 pre-operational (pre-op) sanitation verification in establishments that process meat and poultry carcasses and parts. FSIS personnel are to focus their inspection efforts on those processing areas and equipment that present the highest risk of becoming insanitary or of being the site, or causing, product contamination. This directive provides instructions regarding how to select equipment and areas to inspect, and how to determine to what extent (i.e. how in depth) to perform pre-op verification.

NOTE: IPP who conduct pre-op sanitation verification in slaughter areas are to continue to conduct those procedures as set out in FSIS Directive 5000.1, Appendix 1. Also, these instructions do not eliminate the need to (1) conduct Lock Out/Tag Out; (2) have equipment disassembled, if feasible and if necessary, for thorough inspection; or (3) initiate regulatory control actions as defined in the Rules of Practice (9 CFR 500).

Key points covered:

- The instructions do not apply to IPP in slaughter areas.
- This directive provides instructions to IPP assigned to establishments, or areas of establishments, that conduct any type of processing of meat or poultry carcasses and parts.
- It provides instructions on selecting the areas and equipment to inspect to verify pre-op sanitation because these areas present the highest risk of becoming insanitary or being the site of, or causing, contamination of product.

- It identifies processing areas of an establishment as the facility's production spaces that accommodate the equipment required to accomplish a processing objective

- It provides instruction on how to evaluate the effectiveness of the establishment's pre-operation sanitation activities

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR 416.11 through 416.16
9 CFR 500
FSIS Directive 5000.1, Verifying and Establishment's Food safety System
FSIS Directive 5000.2 Review of Establishment Testing data by Inspection Program Personnel

V. BACKGROUND

FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, describes how IPP are to verify an establishment's implementation of its Sanitation Standard Operation Procedures (SSOP) by performing the 01B02 procedure. The 01B02 procedure has both a Review and an Observation portion. The Review portion requires that IPP conduct their own observations of the sanitary conditions in the establishment and then compare those observations to the establishment's findings. The Observation portion requires that the IPP watch establishment employees perform their monitoring procedures as specified in the establishment's SSOP.

FSIS Directive 5000.1 instructs IPP how to verify that the establishment has effectively implemented its SSOP. In reliance on the general instructions in the FSIS Directive 5000.1, many IPP in processing operations use a random method for selecting processing equipment and areas for inspection pre-op and look only at direct food contact surfaces. This directive provides IPP with specific instructions regarding pre-op inspection. The new instructions address product risk, types of processing areas, and types of equipment.

VI. DEVELOPING A RISK BASED APPROACH TO SELECTING EQUIPMENT AND AREAS TO EXAMINE

A. Gathering Information

1. When conducting the 01B02 procedure, IPP need to focus on direct food contact surfaces. IPP are to evaluate the risks to product by considering the development of insanitary conditions associated with the processing areas within the establishment and with the equipment being used, and the affect that these can have on product. For IPP, decisions regarding the extent of the pre-op sanitation verification need to be based on the conditions observed in the establishment at a given time.

2. Using sound professional judgment, IPP are to gather information to assist them in selecting equipment or areas of the plant for pre-op sanitation verification and for deciding the extent of their pre-op inspection (i.e. how many pieces of equipment, or how many processing areas, they will inspect on a particular day). IPP can use, but are not limited to, the following questions as a mechanism to initiate the process development:

- Which pieces of equipment will directly contact exposed product?
- Which pieces will contact ready-to-eat (RTE) product post lethality?
- Which pieces of equipment are the hardest to clean?
- Which pieces of equipment are easiest to clean?
- Has the sanitary condition of equipment in the processing areas not been verified by FSIS recently?
- Is there a history of 01B02 noncompliances documented by FSIS?
- Does the establishment have a history of finding, and correcting, unclean conditions in processing areas and on equipment?
- How many pieces of equipment or areas of the plant do IPP need to observe to have confidence that the establishment begins operations under sanitary conditions?
- Has an EIAO conducted any verification testing at the establishment, and if so, what were the results?

3. While performing the weekly review of establishment testing records as described in FSIS Directive 5000.2, IPP may gather information that they can consider as part of their selection thought process, and that they can factor into their determination as to whether sanitary conditions prevail at the start of operations. Questions that the IPP are to consider in reviewing establishment records include, but are not limited to, the following:

- Does the establishment conduct any type of swabbing of food contact surfaces, and if so, what have the results been?
- Does the establishment have records that document the cleaning that it does between shifts? Do these records show that the establishment verifies the effectiveness of this cleaning?

4. IPP are to consider whether, based on the information they gather and the results of their verification activities, they need to increase the extent of their pre-op sanitation verification activities. Questions that the IPP might ask include the following:

- Should FSIS increase, or decrease, the extent of pre-op inspection (i.e. how much equipment or how many areas) based on the establishment's testing results, or on historical records?

- Should the extent of pre-op inspection be adjusted based on the establishment's findings or on repetitive noncompliances found by FSIS?

B. Assessing Information Gathered

1. The information gathered from consideration of factors and questions like those presented in Section A will help IPP to develop a thought process for selecting equipment and for determining the extent of pre-op inspection to perform on an on-going basis. Because of the potential contamination risks that some areas and equipment present, a simple random selection method will not be as effective as considering factors such as:

- the complexity of the design of the equipment, specifically considering how hard it is to clean;

- the establishment's sanitation history;

- any documented noncompliances;

- clustered findings of insanitary conditions in particular processing areas or rooms.

2. The equipment that IPP select for examination will vary based on conditions existing in the establishment at any given time. IPP must be knowledgeable about the establishment's processing operations and the complexity of the equipment that the establishment uses. IPP need to be alert to changing conditions and to adjust the selections they make for inspection, as well as the extent of inspection, as needed.

3. IPP can use the following suggested activities to assist them in determining what equipment to select:

- review the 01B02 noncompliance records and establishment SSOP records to determine what areas or equipment are typically being observed as unclean during pre-op verification;

- determine which pieces of equipment are difficult to clean, paying close attention to food contact surfaces;

- consider increasing the number of areas or pieces of equipment to inspect over what has normally been inspected (See Part VI, A, A above) when inspection results indicate that the number of pre-op noncompliances is increasing;

- consider reducing the number of areas or pieces of equipment to inspect to below what is normally inspected (See Part VI, A, 2 above) when inspection results indicate that there is a low number of pre-op noncompliances.

C. Selecting Areas or Equipment for Inspection

Using the information gathered under Part VI.A., IPP are to select the areas and equipment they will inspect. IPP are encouraged to discuss their thought process for making these selections on an on-going basis with their IIC or FLS. IPP are not expected to put this thought process in writing, nor are they required share it with plant management. IPP may need to adjust the thought process periodically based on their verification findings or those documented by the establishment.

VII. PERFORMING 01B02 VERIFICATION

A. Each time IPP perform the Review portion of the 01B02 procedure, they are to use the selection thought process they have developed to choose the equipment and areas that they will include in their pre-op inspection. They are then to follow the 01B02 verification instructions in FSIS Directive 5000.1, Part XV.D.

B. IPP are to perform the 01B02 procedure at the frequency scheduled by PBIS or at an adjusted frequency based on any additional relevant information (see Section VI.A.4 above).

C. IPP are not to:

- look at every piece of equipment when performing the review component of the pre-op 01B02 procedure;

- look at large numbers of simple equipment such as pans, buckets, trays, or hand tools, but instead are to select what they believe to be a representative sample;

- repetitively review equipment following incidental findings such as one small piece of fat or particulate matter on that equipment.

VIII. DETERMINE REGULATORY COMPLIANCE

A. IPP are to inspect for cleanliness areas or equipment that, if insanitary, would present the greatest risk of transferring pathogens or other contaminants to product (e.g., direct food contact surfaces that are difficult to clean or that may serve as harborage sites). When assessing pre-op conditions, IPP are to use professional judgment in assessing whether the establishment’s pre-op measures have resulted in a clean and sanitary environment.

B. IPP are to focus on the following factors in making this assessment:

- Focus on conditions that will have the greatest effect on product (e.g. RTE food contact surfaces and difficult to clean food contact surfaces)

- Look for conditions that may harbor contaminants (e.g. cracked or broken hollow rollers, or the underneath of food contact belts or conveyors that can could contain product residues)

- Consider how the observations made affect overall sanitation of the equipment and the area. For example, consider whether one small piece of fat or product reside is going to affect the sanitation of the food contact surface or contaminate or adulterate product

- Evaluate the establishment's performance over a period of time by reviewing the SSOP records and NRs to determine whether the previous corrective actions implemented by the establishment demonstrate that the SSOP continues to be effective.

NOTE: One incident of non-compliance is not an automatic indication that the SSOP is no longer effective.

X. DOCUMENTATION AND ENFORCEMENT

IPP are to document noncompliances per the instructions in FSIS Directive 5000.1, Chapter IV, Enforcement, and are to initiate enforcement actions in accordance with 9 CFR 500. In addition, when documenting pre-op noncompliances, IPP are to include a description of each noncompliance in clear, concise terms, including the exact problem, time of occurrence, location and effect on product, if any (i.e., how the conditions observed would result in product contamination or adulteration).

XI. DATA ANALYSIS

The District Analyst in each district office will, on a monthly basis, distribute to each Frontline Supervisor a summary report that includes the scheduled and unscheduled 01B02 procedures performed at each establishment in that circuit. The Frontline Supervisor, in discussion with the Deputy District Manager, will ensure that the 01B02 procedure is being performed at the appropriate frequency for each establishment in the circuit. On a biannual basis, the Data Analysis and Integration Group will analyze and report the 01B02 procedures, by HACCP process and HACCP size, to identify any trends needing management review.

Refer questions regarding this directive to the Policy Development Division (PDD) through *askFSIS* at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

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